REMARKS

Claims 1-20 were pending. By this Amendment, claims 1, 13, and 14 are amended, claims 10-12 are canceled, and claims 21-24 are added. As a result, claims 1-9 and 13-24 are now pending in the application.

Amendments to the Specification and Drawings

Several paragraphs of the specification are amended to correct typographical errors. New paragraph [0058.1] and new Fig. 10A are added to highlight more clearly features already shown in Fig. 10. All details shown and described in the new figure and paragraph are fully derived from Fig. 10. The names used for the various elements shown were derived using standard naming conventions well known to those of ordinary skill in the medical arts (i.e., the medial and lateral tines). Accordingly, Applicants have entered no new matter by this Amendment.

Claim Rejections - 35 U.S.C. § 102

Claims 1, 2, 9, and 13-16 were rejected as reading on subject matter anticipated by U.S. Pat. No. 5,906,644 to Powell ("Powell").

Applicants ask the Examiner to reconsider this rejection. Claim 1, as amended, defines a prosthesis in which a cylindrical portion of a spigot is engaged in a cylindrical portion of a bore by a press fit. As recited in this claim, a press fit occurs between the first cylinder of the spigot and a cylindrical portion of the bore. This is a press fit because the diameter of the bore's cylindrical portion is smaller than that of the first cylinder. It is a cylindrical press fit because the two pieces fitted together have cylindrical cross sections.

Powell does not describe a cylindrical press fit. Instead, it describes a tapered press fit between tapered post 22 and tapered bore 18. The press fit is achieved by advancing a threaded locking bolt 34 through tapered bore 18 and post 22 into a threaded aperture 44 (Powell, col. 5, lines 38-48). This arrangement is known as an expanding collet mechanism (col. 5, line 21-22) because the bolt flexes the post so that it presses against the bore.

The difference between a cylindrical press-fit and a taper fit is significant because a cylindrical fit creates a mechanical lock and at the same time allows the two pieces to be

fully seated against one another. A taper fit cannot do both at the same time. The problem with a taper connection is that the axial position of the two parts after assembly cannot be controlled exactly, due to the required manufacturing dimensional tolerances. See Figure A for illustration:

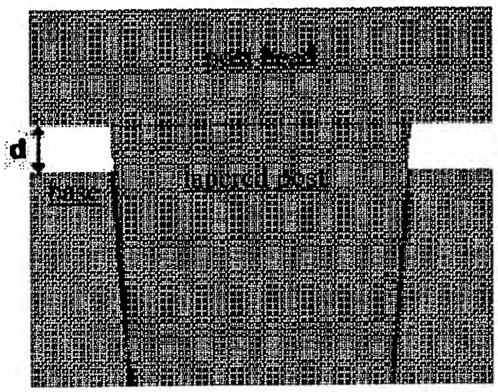


Figure A: taper fit

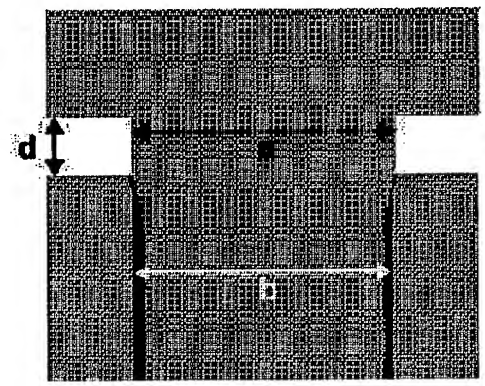


Figure B: cylindrical fit

In order for a taper fit to provide a mechanical lock, the tapered post has to be able to seat as deeply into the tapered bore as necessary to achieve mechanical interference between the tapered sides of the post and bore. The interference can be assured only if the head of the post is given extra clearance so that it does not butt up against the base before the tapers have completely engaged.

The final distance "*d*" between the two parts is dependent on the precise angles and diameters of the two tapered portions. For example, a typical manufacturing tolerance for the taper on a neck trunnion is ±2.5′ (where 60′ equals 1 degree). Together with the same tolerance in a head bore, "*d*" will vary by .25 mm even if every other dimension is made perfectly. While this seems precise, the fact that there is any variability at all means that the parts must be designed such that a gap remains between them (that is, "*d*" in Figure A cannot go to zero). If the gap does go to zero, the taper junction between the two parts is most likely not properly engaged. The need for this gap results in variability in the overall length of the assembly. Moreover, the presence of the gap means that all of the load applied

to the head must pass through the tapered portion, and none of it can be transmitted directly from the head to the base.

In contrast, a cylindrical press-fit connection allows the two parts to seat fully upon assembly. See Figure B for illustration. Notice that the press-fit, and resulting interlock, is achieved because the diameter of the spigot (dimension "a") is greater than the diameter of the hole (dimension "b"). Also, notice that the distance "d" can go to zero because the mating cylindrical surfaces are parallel. The cylindrical post does not have to seat to some critical depth to assure the mechanical interference; the interference exists as soon as the post begins to insert into the bore. As a result, the post head does not need any extra clearance and can be fully seated against the base.

For these reasons, the cylindrical or constant-cross-section press-fit has two advantages over a taper fit. First, the two pieces can be fully seated against one another, so that the total length is predictable. Second, the strength of the assembly is increased by the contact support of one piece by the other because the load is transmitted through the entire contact surface, not just the spigot. Similar press-fits can be achieved with other spigot shapes that have regions with constant cross-sectional geometry.

Powell describes taper fits, not the cylindrical press fit recited in claim 1. For this reason, it does not anticipate the subject matter of claim 1, 2, or 9.

Claim 13 defines a prosthesis in which a locking band of a spigot is to be engaged in a receiving portion of a bore by a press fit. The cross-section of the receiving portion is smaller than that of the locking band, so this is a press fit. The claim requires that both the locking band and the receiving portion have constant cross-sectional geometries along their lengths.

As stated above, Powell describes only tapered press fits. Powell's tapered bore and post do not meet claim 13 because they do not have constant cross-sectional geometries along their length. By definition, a tapered part has a cross-sectional geometry that changes along its length (e.g., large cross-section at the top, small cross section at the bottom). Powell does not describe a press fit in which the interacting parts have constant cross-sectional geometries. For this reason, Powell does not anticipate the subject matter of claims 13-16.

Accordingly, Applicants request withdrawal of the rejection and allowance of claims 1, 2,9, and 13-16.

Claim Rejections - 35 U.S.C. § 103(a)

Claims 3, 4, 10, 11, 17, and 18 were rejected as reading on subject matter made obvious by Powell in view of U.S. Pat. No. 5,653,764 to Murphy.

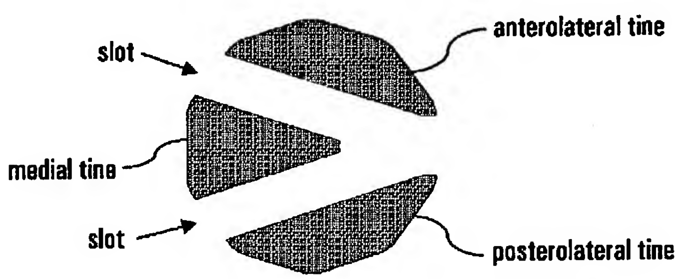
Claim 5 was rejected as reading on subject matter made obvious by Powell in view of U.S. Pat. No. 5,002,578 to Luman.

Claim 6 was rejected as reading on subject matter made obvious by Powell in view of U.S. Pat. No. 5,080,674 to Jacobs et al.

Claims 7, 8, 12, 19, and 20 were rejected as reading on subject matter made obvious by Powell in view of U.S. Pat. No. 5,653,765 to McTighe et al.

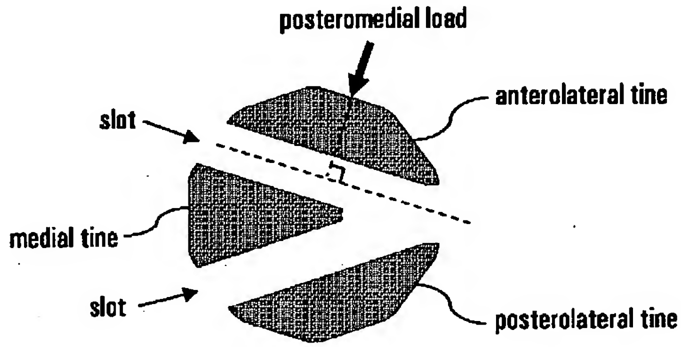
Applicants ask the Examiner to reconsider each of these rejections. Claims 3-8 and 17-18 depend from claims 1 and 13, respectively, which are allowable for the reasons given above. Claims 10-12 have been canceled, so their rejection is irrelevant.

Claims 19 and 20 (and new claims 21-24) relate to a prosthesis stem having a shaft that terminates in tines defined by acutely-angled slots. In one embodiment, shown in Fig. 10 and new Fig. 10A, the shaft terminates in three tines defined by two acutely angled slots. The three tines are termed anterolateral, posterolateral, and medial, in accordance with their anatomic positions when the stem is positioned in a subject:



This arrangement of tines has special significance because the anterolateral tine is shaped and positioned to be optimally flexible. The anterolateral tine of this embodiment will be especially flexible in response to forces that are parallel to its thinnest dimension. This is because the thinnest dimension presents the least resistance to bending forces. Put

another way, the anterolateral tine will be most flexible in response to forces that are approximately perpendicular to the slot that defines the anterolateral tine. Such forces are termed "posteromedial" and act as shown here:



The acute-angle arrangement that creates the anterolateral tine was devised because the loading on the distal end of the stem caused by normal activities, such as walking, is primarily posteromedial when the stem is implanted in the femur. This advantage is discussed in the specification at paragraphs [0021] and [0059].

Although similarly flexible tines could be provided without acute-angled slots, such slots lend themselves to doing so in a particularly beneficial way. As the illustrated embodiment shows, acutely angled slots can be used advantageously to yield the desired flexibility in a device that is symmetrical and can therefore be used in either leg.

In rejecting claims 19 and 20, the Examiner stated:

> At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the tines and slot of the McTighe et al by having at least three tines defined by slots in the shaft, the slots forming an acute angle because Applicant has not disclosed that the three slots forming an acute angle provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the four 90° angle slots shown in Figure 2 [of the McTighe patent] because the McTighe et al reference will perform equally well with the four elongated slots shown in Figure 2 because it will provide the same intended use as the applicants' invention (e.g., it will provide flexibility in torsion, flexibility in different planes, reduce hoop stress and reduce thigh pain). (Office Action, May 27, 2004, page 5)

Applicants ask the Examiner to reconsider this assertion. For the reasons given above, the arrangement of the slots and tines is not an obvious matter of design choice. The McTighe stem will not perform as well as stems defined by claims 19-24, because McTighe's tines are not shaped to provide the flexibility that Applicants achieve by using the claimed subject matter. Independently of the direction in which the load is applied, McTighe's anterolateral tine will not be optimally flexible in response. By taking advantage of the acute-angle slots, Applicants have made their anterolateral tine more flexible for a given stem cross-sectional area. So Applicants' stem component retains the strength of a given cross-sectional area while having superior flexibility. Applicants' invention defined by claim 19 gives them a nonobvious advantage over McTighe's design.

Accordingly, Applicants request the withdrawal of the rejections of claims 3-8 and 17-20.

Applicants invite the Examiner to contact their Agent Scott Kamholz to discuss any matter related to this application. Mr. Kamholz can be reached at 617-832-1176 (direct) or at the telephone number listed below.

Respectfully submitted,
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